[ORAL ARGUMENT NOT YET SCHEDULED]

No. 24-5290

United States Court of Appeals for the District of Columbia Circuit

ARDELYX, INC.; AMERICAN ASSOCIATION OF KIDNEY PATIENTS; NATIONAL MINORITY QUALITY FORUM,

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, ADMINISTRATOR OF CENTERS FOR MEDICARE AND MEDICAID SERVICES; CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Columbia
No. 1:24-cv-02095-BAH (Hon. Beryl A. Howell)

FINAL OPENING BRIEF OF PLAINTIFFS-APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel certify as follows:

A. Parties and Amici

Plaintiffs-Appellants are Ardelyx, Inc. ("Ardelyx"), American Association of Kidney Patients, and National Minority Quality Forum.

Defendants-Appellees are Xavier Becerra, Secretary of Health and Human Services; the United States Department of Health and Human Services; Chiquita Brooks-LaSure, Administrator of Centers for Medicare and Medicaid Services; and Centers for Medicare and Medicaid Services.

There were no other parties, intervenors, or amici before the district court, and no intervenors or amici have appeared in this Court.

B. Rulings Under Review

The rulings under review are (1) the Order Granting Defendants' Motion to Dismiss (Nov. 8, 2024), JA154 (Dkt. 21), and the Memorandum Opinion (Nov. 8, 2024), JA155-87 (Dkt. 22), and (2) the Order Denying Plaintiffs' Motion to Alter Judgment, or in the Alternative, for an Injunction Pending Appeal (Dec. 20, 2024), JA211 (Dkt. 28), and the Memorandum Opinion (Dec. 20, 2024), JA212-38 (Dkt. 29). The district court's first opinion is available at *Ardelyx, Inc. v. Becerra*, No. 24-cv-2095 (BAH), 2024 WL 4723068 (D.D.C. Nov. 8, 2024).

C. Related Cases

This case has not been previously before this Court. Counsel for Plaintiffs-Appellants are not aware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

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RULE 26.1 CORPORATE DISCLOSURE STATEMENTS

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Plaintiff-Appellant Ardelyx, Inc. ("Ardelyx") certifies that following are parent companies, subsidiaries, affiliates, or companies which own at least 10% of the stock of Ardelyx, which have any outstanding securities in the hands of the public: Janus Henderson Group plc. Plaintiff-Appellant American Association of Kidney Patients is a nonprofit organization that has no parent company or stock.

/s/ Michael E. Bern
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Counsel for Plaintiffs-Appellants Ardelyx, Inc. and American Association of Kidney Patients

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Plaintiff-Appellant National Minority Quality Forum certifies that it is a nonprofit organization that has no parent company or stock.

/s/ James E. McCollum, Jr.
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STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs-Appellants respectfully submit that oral argument would materially assist the Court's disposition of this appeal. This case presents important questions of first impression concerning the interpretation of the Medicare Improvements for Patients and Providers Act ("MIPPA"). As interpreted by Defendants-Appellees, the Act will deprive end stage renal disease ("ESRD") patients, including those represented by Plaintiffs-Appellants American Association of Kidney Patients and National Minority Quality Forum, of much-needed access to innovative treatments, such as Plaintiff-Appellant Ardelyx's novel drug, XPHOZAH.

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GLOSSARY

APA	Administrative Procedure Act
CMS	Centers for Medicare and Medicaid Services
ESA	Erythropoiesis Stimulating Agent
ESRD	End Stage Renal Disease
GAO	Government Accountability Office
MIPPA	Medicare Improvements for Patients and Providers Act
PPS	Prospective Payment System

INTRODUCTION

Approximately 550,000 people in the United States suffer from end stage renal disease ("ESRD"), a life-threatening condition in which the kidneys can no longer function on their own. ESRD patients must receive either a kidney transplant or regular dialysis treatment—through which waste is removed from an individual's blood—in order to survive. ESRD patients face staggeringly high health risks, which disproportionately affect low-income, minority, and rural populations.

Because of demonstrable patient need and high coverage costs, Congress over 50 years ago provided that ESRD patients shall receive federal Medicare coverage. In 2008, Congress passed the Medicare Improvements for Patients and Providers Act ("MIPPA") to promote the cost-efficient provision of renal dialysis services by dialysis providers. To that end, Congress created a bundled payment system for "renal dialysis services" under which a single bundled payment under Medicare Part B is made to dialysis facilities for renal dialysis services in lieu of any other separate payment. 42 U.S.C. § 1395rr(b)(14)(A)-(B). Under that ESRD Prospective Payment System ("PPS"), dialysis providers generally receive the same reimbursement per dialysis treatment irrespective of the actual services provided to a patient, or the actual cost of treatment.

Over time, the Centers for Medicare and Medicaid Services ("CMS") has set that bundled payment at an amount that barely covers the cost to dialysis facilities

of providing renal dialysis services. It thereby discourages dialysis facilities from promoting access to novel therapies within the PPS bundle that would increase the cost of care beyond that which CMS is willing to pay.

This appeal concerns CMS's decision to expand the definition of "renal dialysis services" beyond its statutory breaking point—to include a category of drugs that are not administered during renal dialysis, nor by renal dialysis facilities, and which Congress *excluded* from its statutory definition of renal dialysis services. As Plaintiffs-Appellants Ardelyx, American Association of Kidney Patients, and National Minority Quality Forum (collectively, "Plaintiffs") have explained, the forced and unwarranted inclusion of such drugs in the ESRD PPS bundle will discourage the development and adoption of novel therapies and harm patients with significant medical needs. But CMS's decision is not only bad policy, it is contrary to law and in excess of its statutory authority under MIPPA.

When MIPPA was enacted, drugs furnished to patients by dialysis facilities for the treatment of ESRD were generally administered intravenously or by injection during dialysis treatments. Dialysis providers did not historically administer drugs that were only administered orally ("oral-only drugs"). Consistent with that reality, and Congress' focus on making the provision of *renal dialysis services* by *dialysis providers* more cost-effective, Congress defined "renal dialysis services" in MIPPA to encompass only the kinds of drugs that dialysis providers administered during

renal dialysis—or their equivalents. To that end, Congress defined the "renal dialysis services" subject to the PPS bundle to include orally-administered drugs only when they were the "oral equivalent form" of "drugs and biologicals . . . furnished to individuals for the treatment of end stage renal disease"—*i.e.*, when the oral drug was equivalent to an injectable or intravenous drug or biological actually used by a dialysis facility during dialysis. 42 U.S.C. § 1395rr(b)(14)(B)(iii).

Notwithstanding MIPPA's plain text, and over the strong objections of numerous commenters, CMS interpreted MIPPA to cover *all* drugs and biologicals furnished to individuals for the treatment of ESRD, including "drugs and biologicals *with only* an oral form"—*i.e.* oral drugs that were *not* the "oral equivalent form" of drugs or biologicals furnished to individuals for the treatment of ESRD. 42 C.F.R. § 413.171(3) (emphasis added). Many commenters warned that this regulation "represent[ed] a misreading of statutory intent," "violate[d] principles of statutory construction," and would suppress access to and utilization of oral-only drugs. 75 Fed. Reg. 49030, 49032, 49038, 49040 (Aug. 12, 2010). CMS disagreed with those arguments as a matter of public policy. But CMS had no right to adopt an untenable reading of the statute in order to further its policy goals. CMS's decision to place oral-only drugs into the bundle pursuant to 42 C.F.R. § 413.171 is incompatible with the "best reading" of the statute, *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024), and should be rejected.

This case illustrates the consequences of CMS's decision. Ardelyx's drug XPHOZAH is an oral-only drug that is not administered by dialysis providers nor given during dialysis. To the contrary, its label expressly cautions that XPHOZAH should *not* be taken during dialysis. Nonetheless, the district court concluded that CMS was free to designate XPHOZAH and other similarly-situated drugs as "renal dialysis services."

The district court was able to justify that result only by adopting an interpretation of MIPPA that CMS itself never advanced in its rulemaking and that would upend the current administration of the ESRD PPS bundle. Worse still, in an effort to fix the problems its interpretation would cause, the district court interpreted MIPPA to grant CMS effectively unbounded authority to add new categories of "renal dialysis services" to the bundle beyond the four specific categories Congress identified. None of that is tenable, and this Court should reject it.

Finally, XPHOZAH itself does not qualify as a "renal dialysis service" for the additional reason that XPHOZAH is not a drug furnished "for the treatment of end stage renal disease"—a statutory prerequisite to be included in the ESRD PPS bundle. 42 U.S.C. § 1395rr(b)(14)(B). XPHOZAH is indicated to treat hyperphosphatemia (excessive phosphorus in the body), not ESRD. While XPHOZAH is approved for use with *patients* with ESRD, it does not treat ESRD. Nor is CMS's inclusion of XPHOZAH in the bundle consistent with its treatment of

other drugs that treat other causes, complications, or comorbidities of ESRD like hypertension and diabetes.

For all those reasons, this Court should reverse the district court's decision and grant summary judgment to Plaintiffs.

STATEMENT OF JURISDICTION

The district court had jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. On November 8, 2024, the district court issued an Order granting Defendants-Appellees' Motion to Dismiss, JA154 (Dkt. 21), and a corresponding Memorandum Opinion, JA155-87 (Dkt. 22); and on December 20, 2024, an Order denying Plaintiffs-Appellants' Motion to Alter Judgment, or in the Alternative, for an Injunction Pending Appeal, JA211 (Dkt. 28), and a corresponding Memorandum Opinion, JA212-38 (Dkt. 29). Plaintiffs-Appellants filed a timely notice of appeal on December 23, 2024. JA239-40 (Dkt. 30). This Court has jurisdiction under 28 U.S.C. § 1291.

ISSUES PRESENTED

The issues presented are:

1. Whether the district court erred by holding that CMS can define "renal dialysis services" subject to the ESRD PPS bundle to include oral-only drugs that are administered neither during renal dialysis nor by renal dialysis providers, and

fall outside Congress's four enumerated categories of "renal dialysis services" under 42 U.S.C. § 1395rr(b)(14)(B).

2. Assuming the district court so erred, whether the district court should have granted Plaintiffs-Appellants' motion for summary judgment.

STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Factual Background

1. End Stage Renal Disease

Approximately 550,000 people in the United States suffer from ESRD, a life-threatening condition in which the kidneys can no longer function on their own. JA10 (Compl. ¶ 4 (Dkt. 1)); JA87 (Williams Decl. ¶ 4 (Dkt. 14-3)). ESRD is the final, permanent stage of chronic kidney disease, a condition in which the kidneys become progressively damaged over time and eventually lose the ability to function. JA87 (Williams Decl. ¶ 5). Because of the essential role the kidneys play in filtering waste products and toxins from the body, ESRD will result in certain death if left untreated. JA87 (*id.* ¶ 6).

Unless a patient suffering from ESRD is able to obtain a kidney transplant, she must undergo routine dialysis treatment in order to survive. JA87-88 (*id.* ¶ 7). ESRD patients therefore typically undergo dialysis—in which a machine manually

filters waste and excess fluid in place of the kidneys—3 times a week for 3 to 5 hours each session, at a dialysis center. JA88 (*id.* ¶ 8). Even with dialysis, ESRD patients experience frighteningly high mortality rates. 20% to 50% of ESRD patients on dialysis die within 24 months of diagnosis, and the five-year survival rate is approximately 31% to 36%. JA88 (*id.* ¶ 9).

ESRD offers a particularly stark example of the racial, ethnic, and socioeconomic disparities in American healthcare. JA79 (Puckrein Decl. at 3 ¶ 1(Dkt. 14-2)). African Americans are almost 4 times more likely, and Hispanics or Latinos are 1.3 times more likely, to have ESRD than white Americans. JA79 (*id.* at 3 ¶ 3). While African Americans make up 13.5% of the population, they represent more than 35% of dialysis patients, and are more likely to die from ESRD than white patients. JA79 (*id.* at 3 ¶¶ 4-5). ESRD is often caused by other underlying, uncontrolled health conditions, like high blood pressure and diabetes. JA79 (*id.* at 3 ¶ 6). As a result, underlying disparities in healthcare treatment impacting minorities and low-income individuals exacerbate disparities in who develops and dies from ESRD.

2. Medicare Coverage For End Stage Renal Disease

In 1972, in response to growing ESRD patient numbers and the high cost of dialysis treatment, Congress extended Medicare coverage to individuals suffering from ESRD, without regard to age or disability. *See* An Act to Amend the Social

Security Act, and for Other Purposes, Pub. L. No. 92-603, 86 Stat. 1329 (1972); 42 U.S.C. § 426-1(a); JA69 (Clynes Decl. ¶ 6 (Dkt. 14-1)).

Beginning in the 1980s, Medicare began paying for dialysis services using the composite rate system, a blended prospective payment and fee-for-service system. Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2145, 95 Stat. 357, 799-800 (1981). Under that system, dialysis facilities received a single, prospectively determined payment per treatment to cover costs including a defined set of regularly provided tests and supplies, as well as a narrow set of injectable drugs associated with dialysis. *See id.*

In addition to the composite rate, dialysis facilities were separately reimbursed for each use of injectable ESRD drugs with payments under Medicare Part B, which generally covers drugs that patients would not administer themselves. JA93 (Williams Decl. ¶ 42). Orally administered drugs, by contrast, were covered separately under Medicare Part D, which offers prescription drug coverage for self-administered drugs. *Id.*; 75 Fed. Reg. at 49040.

3. The Creation Of The Modern ESRD PPS Bundle

In 2008, Congress enacted MIPPA. MIPPA directs CMS to implement a bundled payment system for "renal dialysis services" under which a single payment is made to dialysis facilities for certain items, drugs, and tests, in lieu of any other separate payment for these materials. 42 U.S.C. § 1395rr(b)(14)(A)-(B). Under the

ESRD PPS bundle, dialysis facilities receive—in general—the same amount per dialysis treatment per patient, regardless of the specific cost to treat that patient. *See* CMS, *End Stage Renal Disease (ESRD) Prospective Payment System (PPS)* (last modified Nov. 5, 2024).[1]

Congress's expectation for the bundled payment was that it would lead dialysis facilities to operate more efficiently because the provider would "retain the difference if Medicare's payment exceeds the costs they incur to provide the services." Government Accountability Office ("GAO"), *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for all ESRD Services Would Promote Efficiency and Clinical Flexibility* 22 (GAO-07-77, Nov. 2006).[2] In practice, however, CMS has come to set the bundled payment rate at an amount that barely covers a dialysis facility's cost of care. JA12 (Compl. ¶ 9); JA99 (Williams Decl. ¶ 66). In 2023, the Medicare Payment Advisory Commission, a nonpartisan legislative-branch agency, even calculated that the bundled payment and the rising cost of care resulted in dialysis facilities experiencing *negative margins* when

[1] https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd.

[2] https://www.gao.gov/assets/gao07-77.pdf.

treating Medicare patients. JA45 (Compl. ¶ 172); *see* Medicare Payment Advisory Comm'n, Report to the Congress, Medicare Payment Policy 194 (Mar. 2023).[3]

Congressional leaders have also criticized CMS for failing to "sufficiently reimburse for new, innovative products." JA12 (Compl. ¶ 10) (citation omitted); *see* Letter from Cong. Kidney & Health Care Innovation Caucuses, to Chiquita Brooks-LaSure, Adm'r, CMS (Oct. 2, 2023) ("Congressional Kidney Letter").[4] Following a short period in which CMS may temporarily provide additional reimbursement to dialysis facilities for their use of new drugs, CMS withdraws that reimbursement in favor of small adjustments to the bundled rate—adjustments that need not support the full cost of acquiring and administering the treatment. JA12 (Compl. ¶¶ 9-10); 89 Fed. Reg. 55760, 55797 (July 5, 2024); Congressional Kidney Letter at 1-2, *supra*. In many cases, moreover, the bundled rate remains unchanged when the reimbursement for the innovative therapy is withdrawn. As a consequence, dialysis facilities are disincentivized from adopting novel drugs that would increase their cost of treatment beyond the bundled payment amount. This financial challenge causes dialysis facilities to "hesitate to adopt new products" and diminishes patients' long-

[3] https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_v2_SEC.pdf.

[4] https://kidneycarepartners.org/wp-content/uploads/2023/10/CY24-ESRD-Innovation-Letter-Final.pdf.

term access to needed medical care. JA12 (Compl. ¶ 10) (quoting Congressional Kidney Letter at 2, *supra*).

4. CMS Acts To Add Oral-Only Drugs Into The ESRD PPS Bundle

The ESRD PPS bundled "single payment is made . . . for renal dialysis services (as defined in subparagraph (B))." 42 U.S.C. § 1395rr(b)(14)(A)(i). Congress defined the set of "renal dialysis services" for which dialysis providers receive a bundled payment as follows:

> For purposes of this paragraph, the term "renal dialysis services" includes—
>
> (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;
>
> (ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;
>
> (iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and
>
> (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Id. § 1395rr(b)(14)(B).

Under the statute's express terms, orally-administered drugs qualify as "renal dialysis services" only when they are (1) oral forms of erythropoiesis stimulating agents ("ESAs") under clause (ii); or (2) "oral equivalent forms" of "other drugs and biologicals that are furnished to individuals for the treatment of [ESRD]" under clause (iii). That accords with the fact that dialysis facilities have not historically administered "oral-only" drugs to ESRD patients, let alone as part of dialysis. JA93-94 (Williams Decl. ¶¶ 42, 45, 47-49). As a result, there would have been little need to account for the cost of oral-only drugs in the bundled payment made *to dialysis facilities* for *dialysis treatment*. *Id.* And unless such oral-only drugs were equivalent to injectable drugs that would otherwise be administered by dialysis facilities, inclusion of such drugs within the bundled payment would not promote the efficient use of resources by dialysis facilities when providing dialysis.

In 2009, CMS issued a proposed rule to implement the bundled payment system created by MIPPA beginning in 2011. 74 Fed. Reg. 49922, 49922 (Sept. 29, 2009). Despite the fact that Congress directed that only a subset of orally administered drugs be included within the bundle, CMS proposed to interpret 42 U.S.C. § 1395rr(b)(14)(B) so as to include *all* drugs and biologicals furnished to individuals for the treatment of ESRD, including those with only an oral form.

CMS justified the inclusion of oral-only drugs in the regulatory definition of "renal dialysis services" on policy grounds. It reasoned that "the exclusion of oral

drugs . . . for which there is no injectable equivalent (or other non-oral form of administration) from the ESRD PPS would defeat one of the very *purposes* of the new system—the inclusion of all renal dialysis services furnished to ESRD patients in a comprehensive payment bundle to which a reasonable payment amount can be attached empirically." *Id.* at 49928 (emphasis added). CMS also rationalized that "the exclusion of oral drugs and biologicals for which there is no injectable (or other non-oral) version does not make sense from a payment-policy perspective," as it could over time result in the growth of services excluded from the bundle. *Id.*

CMS sought to square its newly proposed regulation with the statute. It posited that 42 U.S.C. § 1395rr(b)(14)(B)(iii) defines "renal dialysis services" to include "[o]ther drugs and biologicals . . . for which payment was (before the application of this [paragraph]) made separately under this title and any oral equivalent form of such drug or biological." *Id.* at 49927-28. CMS found the reference to "this title" to "requir[e] the inclusion in the ESRD PPS payment bundle" of any drug that would have been payable under Medicare Part B and D, including oral-only drugs, prior to the application of MIPPA. *Id.* at 49928. CMS acknowledged that "an alternative reading of the last part of clause (iii) with respect to the phrase 'and any oral equivalent form of such drug or biological' could be interpreted to limit the scope of the drugs and biologicals included in the bundle to *only oral versions of injectables* (or other non-oral routes of administration)." *Id.*

(emphasis added). CMS rejected that reading, however, as "unduly constrained." *Id.* Instead, it interpreted clause (iii) to "include *all* drugs and biologicals" used to treat ESRD that would have been separately payable under either Medicare Part B or Part D, "regardless of the route of administration." *Id.* (emphasis added). CMS also briefly suggested that subpart (B)(iv) of the definition of "renal dialysis services," which addresses "other items and services not covered in clause (i)," provided catch-all "authority to include all drugs and biologicals, including oral-only drugs and biologicals, used to treat ESRD in the ESRD PPS payment bundle." *Id.* (citation omitted).

Most comments on the proposed regulation opposed the inclusion of oral-only drugs in the bundle, and "[m]any" focused on CMS's improper expansion of the statutory definition to include these oral-only drugs. *See* 75 Fed. Reg. at 49038 (criticizing CMS's reading as "a misreading of statutory intent and violat[ing] principles of statutory construction"). In questioning CMS's proposal, various commenters noted that the statute "focuses on payments to ESRD facilities," and argued "that the four categories of renal dialysis services specified in [§ 1395rr(b)(14)(B)] only pertain to services furnished for which payment is made to ESRD facilities." *Id.* Because oral-only drugs were not provided by dialysis facilities and were instead obtained from pharmacists for self-administration,

commenters argued that they did not fit within the four categories of "renal dialysis services" described by the statute.

Commenters also criticized CMS's construction of clause (iv) to encompass any drugs for the treatment of ESRD not included in clause (i), noting that such a construction "violates a principle of statutory construction, by making clauses (ii) and (iii) otherwise redundant." *Id.* at 49039. CMS acknowledged that under its reading, "several of the clauses of the definition could be viewed as superfluous," but suggested that the statute should be read broadly to "wrap[] in all items and services related to outpatient renal dialysis that are furnished to individuals for the treatment of ESRD." *Id.* at 49040.

Many commenters expressed concern that CMS's proposed regulation would undermine the statute's purpose and harm patients, explaining that because dialysis providers "would be liable for the difference if costs exceeded Medicare payments," adding oral-only drugs into the bundle would result in "unintended clinical consequences for patients as ESRD facilities seek to maximize profits by resorting to cheaper but less effective alternatives" to oral-only drugs. *Id.* at 49032, 49040. CMS admitted that including oral-only drugs in the bundle could indeed result in "underutilization." *Id.* at 49041. CMS nonetheless proceeded with a final rule and codified its regulatory definition of "renal dialysis services" as including all oral-only drugs furnished for the treatment of ESRD at 42 C.F.R. § 413.171. But, perhaps

recognizing its rule could have a radical impact on dialysis facilities and patients, CMS decided to delay the inclusion of oral-only drugs in the bundle until 2014. *Id.* at 49043-44.

5. Congress Repeatedly Delays The Inclusion Of Oral-Only Drugs In The ESRD PPS Bundle

Congress repeatedly delayed CMS's plan to place oral-only drugs into the bundled payment system. In 2012, Congress prevented CMS from including oral-only drugs in the bundle until January 1, 2016. *See* American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 632(b), 126 Stat. 2313, 2354 (2012). In 2014, Congress again delayed the inclusion of oral-only drugs until 2024 through the Protecting Access to Medicare Act of 2014. Pub. L. No. 113-93, § 217(a)(1), 128 Stat. 1040, 1061 (2014). Later that same year, Congress delayed the implementation until 2025. *See* Achieving a Better Life Experience Act of 2014, Pub. L. No. 113-295, § 401, 128 Stat. 4010, 4056 (2014).

In response to this legislation, CMS updated its regulations to state that "[e]ffective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS . . . and separate payment will no longer be provided." 42 C.F.R. § 413.174(f)(6).

Therefore, despite CMS's initial 2011 rulemaking, stakeholders have not had to contend with CMS's regulation until recently, as the 2025 effective date approached.

6. Ardelyx's XPHOZAH

Many ESRD patients suffer from a variety of comorbidities, including hypertension, diabetes, cardiovascular disease, and hyperphosphatemia—the condition of having too much phosphate in the body. JA88-89 (Williams Decl. ¶¶ 12-14, 18). Hyperphosphatemia is associated with a higher risk of cardiovascular mortality, and it can also lead to the progression of bone disorders. JA89 (*id.* ¶ 19). Managing phosphate levels is therefore very important. JA89 (*id.* ¶ 20).

Approximately 80% of ESRD patients on maintenance dialysis have hyperphosphatemia. JA89 (*id.* ¶ 18). A substantial number of ESRD patients do not have hyperphosphatemia, however. *Id.* And some patients have hyperphosphatemia, but not ESRD. *Id.* Indeed, one study found hyperphosphatemia in roughly one out of eight patients admitted to a hospital—*excluding* patients with ESRD. Charat Thongprayoon et al., *Admission Hyperphosphatemia Increases the Risk of Acute Kidney Injury in Hospitalized Patients*, J. Nephrology 241-47 (2018).[5]

[5] *See also* James L. Lewis III, *Hyperphosphatemia*, Merck Manual (rev. Sept. 2023), https://www.merckmanuals.com/professional/endocrine-and-metabolic-disorders/electrolyte-disorders/hyperphosphatemia (noting causes other than ESRD).

In this way, hyperphosphatemia is much like hypertension and diabetes: Many patients with ESRD also have these conditions; some patients with ESRD do not have these conditions; and some patients without ESRD have these conditions. *See* JA88 (Williams Decl. ¶ 13).

Nephrologists generally manage hyperphosphatemia by prescribing a range of phosphate-lowering therapies. As first-line therapies, many patients are prescribed phosphate binders, which lower phosphate levels by binding to excess phosphate molecules in the gastrointestinal tract and preventing them from reaching the bloodstream. JA90 (*id.* ¶ 22). But not all patients have an adequate response to phosphate binders, meaning their blood phosphate levels are still too high. JA90 (*id.* ¶ 24). Indeed, approximately 70% of ESRD patients are unable to maintain target phosphate levels despite treatment with phosphate binders. JA90 (*id.* ¶ 25).

Enter XPHOZAH, a novel therapy developed by Ardelyx that reduces serum phosphorus levels. XPHOZAH first became available to patients in October 2023 following approval by the FDA. JA90 (*id.* ¶ 28). XPHOZAH is a first-in-class phosphate absorption inhibitor. Unlike phosphate binders, XPHOZAH *blocks* phosphate absorption at the primary cellular pathway. JA91 (*id.* ¶ 30). XPHOZAH provides the first new mechanism of action to reduce phosphate in over five decades. *Id*. XPHOZAH is "indicated to reduce serum phosphorus in adults with chronic kidney disease . . . on dialysis as add-on therapy in patients who have an inadequate

response to phosphate binders or who are intolerant of any dose of phosphate binder therapy." JA103-13 (Williams Decl. Ex. 1 (Dkt. 14-4)).

XPHOZAH is not distributed or administered by dialysis facilities, nor is it taken during dialysis. JA92 (Williams Decl. ¶ 39). Instead, like other phosphate-lowering therapies pre-January 2025, XPHOZAH was prescribed by nephrologists and distributed through pharmacy providers. *Id.* While dialysis is typically performed three times a week, XPHOZAH is taken twice daily, just prior to the first and last meals of the day. JA92 (*id.* ¶ 37). Like all other current phosphate-lowering therapies, XPHOZAH must be orally ingested. JA91-92 (*id.* ¶ 33). XPHOZAH is not administered as part of the delivery of maintenance dialysis. JA92 (*id.* ¶¶ 35-39). In fact, XPHOZAH's label makes clear "[p]atients should be counseled not to take XPHOZAH right before a hemodialysis session." JA92 (*id.* ¶ 37). Before January 1, 2025, XPHOZAH was covered under Medicare Part D, like other self-administered drugs. JA96 (*id.* ¶ 54); JA60-61 (Compl. Ex. 1 at 1-2 (Dkt. 1-1)); JA138-39 (Williams Decl, Ex. 3 at 3-4 (Dkt. 14-6)).

On May 13, 2024, CMS sent a letter to Ardelyx, stating that "CMS has identified XPHOZAH to be a renal dialysis service under 42 CFR 413.171, because it is furnished to individuals to treat a condition associated with ESRD and is

essential to the delivery of maintenance dialysis." JA60 (Compl. Ex. 1 at 1).[6]

B. Procedural History

1. District Court Proceedings

On July 17, 2024, Plaintiffs filed this litigation, asserting that CMS's oral-only drug regulation and its XPHOZAH decision violated the APA.

Plaintiffs attempted to negotiate a schedule for expedited cross-motions for summary judgment. JA65 (Mot. Prelim. Inj. 5 n.1 (Dkt. 14)). But Defendants instead filed a motion to dismiss. 42 U.S.C. § 1395rr(b)(14)(G); JA62-63 (Mot. Dismiss ("MTD") (Dkt. 11)). Plaintiffs sought a preliminary injunction two days later. JA65 (Mot. Prelim. Inj. 5 n.1).

Defendants argued that Congress directed in subparagraph (G), that there be "no judicial review of . . . the identification of renal dialysis services." 42 U.S.C. § 1395rr(b)(14)(G). However, as the district court correctly found, preclusion of review of any type of agency action "'extends no further than the Secretary's statutory authority to' take the action." JA168 (Mem. Op. Granting Mot. Dismiss 14 ("MTD Op.") (Dkt. 22)) (quoting *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir.

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[6] Under CMS rules, "[r]enal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis." 42 C.F.R. § 413.171(5). As Ardelyx noted below, it is impossible to understand CMS's determination that XPHOZAH is "essential for the delivery of maintenance dialysis" when XPHOZAH's label specifically instructs patients not to take XPHOZAH prior to dialysis, and XPHOZAH is neither administered during dialysis nor by dialysis providers.

2004)). Thus, as the district court explained, "[t]o 'determine whether [a] judicial-review bar applies in [any] case,' the court 'must decide whether the challenged agency action counts as' the specific action for which the bar precludes review." *Id.* (alterations in original) (quoting *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020)). "Otherwise, agencies could characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend." *Id.* (quoting *Amgen*, 357 F.3d at 113). Accordingly, the district court held that the jurisdictional inquiry "merge[d] with the merits" because Plaintiffs' "challenge to the [agency's] action raise[d] the question of the [agency's statutory] authority." *Id.* (first and third alteration in original) (quoting *Amgen*, 357 F.3d at 113-14). The court could therefore "'skip to the merits question' of compliance with the statute." *Id.* (quoting *Am. Hosp.*, 964 F.3d at 1238-39).

Reaching that question, the district court held that CMS had lawfully included oral-only drugs in the ESRD PPS bundle pursuant to its statutory authority. The court reasoned that such drugs were covered by subpart (B)(iii) of the definition of "renal dialysis services" based on an interpretation of that clause that CMS had never previously advanced. JA177-79 (*id.* at 23-25). Although the court's reading of (B)(iii) excluded many drugs, the court added that the definition of "renal dialysis services" was not limited to the four specific categories that Congress laid out in clauses (i)-(iv). JA175-76 (*id.* at 21-22). Noting that Congress introduced the four

enumerated categories of renal dialysis services "with the term 'includes,'" the court concluded that the "enumerated categories [were] not exhaustive and others [were] not foreclosed." JA175 (*id.* at 21) (quoting 42 U.S.C. § 1395rr(b)(14)(B)). The court therefore held that CMS had (apparently unbounded) authority to expand the definition of "renal dialysis services," including to particular drugs that the court's interpretation of subpart (B)(iii) would have excluded.

Having found that the agency had acted within the scope of its statutory authority, the court granted Defendants' motion to dismiss and denied as moot the motion for a preliminary injunction. JA187 (*id.* at 33).

On November 20, 2024, Plaintiffs filed a motion to alter judgment, or in the alternative for an injunction pending appeal, arguing that the district court's construction of 42 U.S.C. § 1395rr(b)(14)(B)(iii) was incompatible with even the Government's own construction and longstanding application of the statute and would require removing numerous drugs from the bundle. JA196-208 (Mot. Alter J. 2-14 (Dkt. 23)). Alternatively, Plaintiffs sought an injunction pending appeal before CMS's oral-only drug policy went into effect on January 1, 2025.

The district court denied that motion on December 20, 2024. JA212-38 (Mem. Op. Denying Mot. Alter. J. (Dkt. 29)). The court did not dispute that its construction of subpart (B)(iii) would leave out numerous drugs that CMS had included in the bundle. In its view, however, by defining renal dialysis services to "include" four

categories, Congress had signaled that that those four categories were intended to be "non-exhaustive." JA217 (*id.* at 6). The court thus reiterated that CMS was free to define "renal dialysis services" to include drugs that Congress had not expressly included, even when—as here—those drugs are not administered during renal dialysis at all.

The court also denied Plaintiffs' motion for an injunction pending appeal. JA234-38 (*id.* at 23-27). The court acknowledged Plaintiffs' argument that CMS's rule would diminish patients' access to XPHOZAH, resulting in worse outcomes for ESRD patients. JA236 (*id.* at 25). And the court acknowledged that "Plaintiffs do call out troubling real-world examples" where similar results followed a drug's addition to the ESRD PPS bundle. JA237 (*id.* at 26). The court nonetheless denied relief, reasoning that such outcomes were uncertain. JA236-37 (*id.* at 25-26).

2. Appellate Proceedings

On December 23, 2024, Plaintiffs filed a timely notice of appeal and sought an emergency injunction pending appeal in this Court, requesting that this Court enjoin enforcement of CMS's oral-only drug policy pending appeal before it went into effect on January 1, 2025. *See* Doc. 2091334. This Court issued an emergency briefing schedule and subsequently denied that motion on December 31, 2024 in an unsigned per curiam order. *See* Order (Dec. 31, 2024) (Doc. 2091992) (stating only that "Appellants have not satisfied the stringent requirements for an injunction

pending appeal"). Because CMS's oral-only drug policy is now in effect, Plaintiffs no longer seek a preliminary injunction to prevent the policy from taking effect. Nevertheless, given the harms to patients and Ardelyx that are occurring while the policy remains in effect, Plaintiffs believe that speedy resolution of this appeal remains essential.

SUMMARY OF ARGUMENT

The district court's grant of dismissal should be reversed and summary judgment granted in Plaintiffs' favor. Congress defined "renal dialysis services" to include four specific categories of drugs, items, and services. Congress did not grant CMS authority to render those specific categories meaningless by redefining that term, much less to do so without any judicial oversight whatsoever.

I. This Court has jurisdiction to reach the merits of Plaintiffs' claim. Although Congress generally barred judicial review of CMS's "identification of renal dialysis services included in the bundled payment," 42 U.S.C. § 1395rr(b)(14)(G), a regulation *redefining* the term "renal dialysis services" to include categories far beyond those established by Congress, well before the identification of any particular drug as a "renal dialysis service," does not qualify. In any event, this Court has repeatedly held that where the plaintiff's claim is that the agency has exceeded its statutory authority under the preclusion provision,

jurisdiction and the merits merge. Thus, as the district court correctly recognized, this Court can and must reach the merits.

II. On the merits, the district court erred in holding that CMS's oral-only drug policy was lawful. Oral-only drugs do not fall within any of the four specific categories of "renal dialysis services" that Congress defined. The district court held that they fell within subpart (B)(iii) of the statutory definition but it did so only by adopting an interpretation that CMS never advanced in its rulemaking, that is inconsistent with longstanding Government practice, and that would exclude numerous treatments currently in the ESRD PPS bundle from that bundle. When confronted with this problem, the district court endeavored to fix it by stating that CMS had wide-ranging authority to add new categories of "renal dialysis services" under the statute because the statue uses the word "includes" to introduce the four specific subparts of the definition of "renal dialysis services." But this Court has long held that agencies cannot ignore Congress's specific constraints by relying on alleged catch-all authority. Thus, CMS cannot use any residual authority it might have to redefine "renal dialysis services" in a manner inconsistent with the four specific subparts of Congress's definition of "renal dialysis services" and with the plain meaning of "renal dialysis services" itself.

III. Finally, even assuming oral-only drugs generally can count as "renal dialysis services," XPHOZAH cannot because it is not "furnished . . . for the

treatment of [ESRD]" as required by the statute. *See* 42 U.S.C. § 1395rr(b)(14)(B)(iii)-(iv). XPHOZAH treats hyperphosphatemia, not ESRD. Other drugs that treat comorbidities of ESRD, such as diabetes and hypertension, are not included in the ESRD PPS bundle, and XPHOZAH must be treated similarly.

STANDARD OF REVIEW

This Court "review[s] the district court's order granting the motion to dismiss *de novo*." *Carter v. Washington Metro. Area Transit Auth.*, 503 F.3d 143, 145 (D.C. Cir. 2007).

ARGUMENT

This Court has jurisdiction to find that CMS's oral-only drug rule violates the governing statute. To be sure, Congress provided that there shall be "no . . . judicial review of . . . the identification of renal dialysis services." 42 U.S.C. § 1395rr(b)(14)(G). But CMS's regulation *redefining* "renal dialysis services" to include an entirely new category of drugs outside the four categories that Congress defined is not an "*identification* of renal dialysis services." Thus, the preclusion provision does not apply. In any event, as the district court correctly recognized, to determine whether the preclusion provision applies, this Court must decide whether the challenged action exceeds CMS's statutory authority. JA168 (MTD Op. 14) (citing *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020)). In that sense, the jurisdictional inquiry "merge[s] with the merits." *Id.*; *see Amgen, Inc. v.*

Smith, 357 F.3d 103, 113 (D.C. Cir. 2004) (finding "consideration of the legality of the [agency's] action [and] consideration of this court's jurisdiction" "merge[]").

On the merits, Congress defined "renal dialysis services" to cover four specific categories of items, drugs, and services provided by dialysis facilities during dialysis. 42 U.S.C. § 1395rr(b)(14)(B). Oral-only drugs, which are administered neither by renal dialysis providers nor during renal dialysis, do not qualify under a plain reading of the statute's four categories. The district court's deeply flawed opinion evinces a misunderstanding of the statute's text and structure and should be reversed.

I. THE PRECLUSION PROVISION DOES NOT BAR REVIEW OF THE MERITS

"There is a 'strong presumption that Congress intends judicial review of administrative action,'" especially "action taken in excess of delegated authority." *Amgen*, 357 F.3d at 111 (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). That presumption "can only be overcome by a 'clear and convincing evidence' that Congress intended to preclude the suit." *Id.* (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967)). The "burden" to show jurisdiction has been stripped by "'clear and convincing evidence'" falls on the "government[]." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 825 (D.C. Cir. 2020) (alteration in original) (citation omitted), *rev'd and remanded on other grounds sub nom. Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022). And the Government cannot

meet that burden where "the wording of a preclusion clause is less than absolute" and does not clearly cover the particular suit at issue. *Amgen*, 357 F.3d at 112 (citation omitted).

The Government cannot meet its heavy burden to show that this Court lacks jurisdiction for two reasons. First, the preclusion provision does not apply to challenges to rules redefining the phrase "renal dialysis services." And second, the preclusion provision does not apply when the agency exceeds its statutory authority.

A. The Preclusion Provision Applies To Identifications, Not Redefinitions

To determine whether judicial review is precluded, the Court must first decide whether, under its plain text, "the provision of the statute that limits judicial review is . . . applicable." *COMSAT Corp. v. FCC*, 114 F.3d 223, 226 (D.C. Cir. 1997). Here, it is not. Subparagraph (G) limits judicial review of the agency's "identification" of a *particular* renal dialysis service—*e.g.*, a *specific* item, service, or drug—that falls within the statutory definition of "renal dialysis services." It does not preclude a challenge to CMS's adoption of a regulation that *expands the definition* of "renal dialysis services" beyond that which Congress authorized.

While CMS's issuance of a regulation expansively redefining "renal dialysis services" might amount to the "interpretation" or "construction" of that phrase, it certainly does not amount to the "identification" of renal dialysis services. 42 U.S.C. § 1395rr(b)(14)(G). The term "identification" connotes the classification of a

specific object. *See Identify*, *Merriam Webster Dictionary*, https://www.merriam-webster.com/dictionary/identify (last visited Jan. 31, 2025) (to "state the identity of . . . something"). To "'identify an object' . . . means 'to recognize or establish an object as being a particular thing.'" *Apple Inc. v. Omni MedSci, Inc.*, No. 2023-1034, 2024 WL 3084509, at *5 (Fed. Cir. June 21, 2024) (citation omitted). "[I]dentification of renal dialysis services" thus means identifying a particular drug or treatment as a "renal dialysis service" within the meaning of the statute. 42 U.S.C. § 1395rr(b)(14)(G). The challenged regulation here does not count as an identification because it does not purport to identify any particular drug or treatment as a "renal dialysis service"; instead, it purports to *redefine* the meaning of "renal dialysis services" altogether. The preclusion provision thus does not apply.

The district court rejected this reading of the preclusion provision, *see* JA167 (MTD Op. 13), but it pointed to no caselaw suggesting that the phrase "identification" could sweep more broadly to cover regulations redefining the meaning of "renal dialysis service." Instead, it pointed only to a single dictionary definition, which states that "identify" means to "recognize . . . something and say or prove . . . what that . . . thing is." *Id.* (alterations in original) (quoting *Identify*, *Cambridge Dictionary*, https://dictionary.cambridge.org/us/dictionary/english/identify) (last visited Jan. 31, 2025). But that dictionary definition just underscores *Plaintiffs*' point: to identify "some*thing*" means to say "what that . . . *thing* is." In

other words, the act of identification is item-specific; it does not encompass redefining the relevant category into which specific items are meant to be placed.

It is one thing to suggest that Congress intended to limit judicial review of challenges to an agency decision that a particular service falls within one of the enumerated categories of "renal dialysis services" that Congress itself identified. It is quite another to suggest that Congress intended to prevent judicial review of an agency's attempt to substitute its own judgment for Congress's with respect to the definition of those categories. This Court should therefore hold that the preclusion provision does not bar review in this case and proceed to the merits.

B. Alternatively, Jurisdiction And The Merits Merge

Alternatively, even if this Court agrees with the district court that the preclusion provision's reference to "identification" can sweep broadly enough to cover CMS's redefinition of "renal dialysis services," the provision still does not bar review of the merits where, as here, CMS has exceeded its statutory authority. Thus, as the district court correctly held, jurisdiction and the merits merge in this case.

1. The District Court Correctly Held Jurisdiction And The Merits Merge

As this Court has made clear, provisions like subparagraph (G) "prevent review *only* of those [determinations] that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of [determinations] extends no further than the Secretary's statutory authority to make them." *Amgen*, 357 F.3d at

112 (emphasis added). Because CMS lacks statutory authority to rewrite the statutory definition of "renal dialysis services" to create a regulatory definition broader than the one Congress enacted, subparagraph (G) does not prevent review of Plaintiffs' challenge.

Thus, as the district court correctly recognized, jurisdiction and the merits "merge" in this case. JA168 (MTD Op. 14); *see Amgen*, 357 F.3d at 113 (where "the determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action," "the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review").

American Hospital Association v. Azar is instructive. There, the plaintiffs argued that the Department of Health & Human Services had acted in excess of its statutory authority when it reduced certain reimbursement rates for outpatient services. The Government responded that the Court lacked jurisdiction because the Medicare statute precluded review of agency decisions related to reimbursement for outpatient services, including "the establishment of . . . methods described in paragraph 2(F)." 964 F.3d at 1237-38 (alteration in original) (citation omitted). But the plaintiffs' core claim was that the challenged rate reduction was "*not* a 'method[] described in paragraph 2(F).'" *Id.* at 1238 (alteration in original) (citation omitted). Thus, "to determine whether the judicial-review bar applie[d]," the Court had to

answer the merits question presented by the plaintiffs' suit. *Id.* As the Court explained, if the plaintiffs were right that the agency "ha[d] acted outside the scope of its statutory mandate," then the Court would "have jurisdiction." *Id.* (citation omitted). "Put differently, 'the jurisdiction-stripping provision does not apply' if the agency's action fails to qualify as the kind of action for which review is barred." *Id.* (citation omitted). Thus, if the Court "'find[s] that [the agency] has acted outside the scope of its statutory mandate, [the Court] also find[s] that [it] ha[s] jurisdiction,'" and "the court can simply skip to the merits question in its analysis." *Id.* (alterations in original) (citation omitted).

This Court has also explained why courts must reach the merits of whether an agency has exceeded its delegated authority before applying a preclusion provision: Were the law otherwise, "agencies could characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend." *Amgen*, 357 F.3d at 113. This Court has "categorically reject[ed]" the assumption that an agency "possesses plenary authority to act within a given area simply because Congress has endowed it with some authority to act in that area." *COMSAT*, 114 F.3d at 227 (citation omitted).

Ensuring the agency has acted within its statutory authority is especially important with high-stakes preclusion provisions like this one: Since the preclusion provision here applies to both "administrative [and] judicial review" of agency

action, 42 U.S.C § 1395rr(b)(14)(G), applying the provision would prevent even internal appeals to higher authority within CMS, *see* JA59-61 (Compl. Ex. 1) (CMS offering no right of appeal); *Ascension Borgess Hosp. v. Becerra*, 557 F. Supp. 3d 122, 127 (D.D.C. 2021) (noting that CMS had denied internal appeal due to similar preclusion provision), *aff'd*, 61 F.4th 999 (D.C. Cir. 2023). Thus, policing the boundaries of the preclusion provision is essential to ensure that the agency is not acting outside its congressionally delegated authority without any check—even an internal agency one—on its power.[7]

2. Defendants' Arguments To the Contrary Are Unpersuasive

Defendants contend that subparagraph (G) bars review of any regulation purporting to identify a renal dialysis service, regardless of whether that regulation falls within Congress's definition of a "renal dialysis service" or exceeds the agency's statutory authority. *See* Opp. to Emergency Stay Appl. 15-17 & n.1 (Dec. 29, 2024) (Doc. 2091774). Even the district court declined to accept that interpretation of subparagraph (G). For good reason. As the court explained, application of subparagraph (G) "cannot turn solely on CMS's say-so." JA169 (MTD Op. 15). If it did, CMS could redefine "renal dialysis services" to mean *all* drugs

[7] That is not to say that the preclusion provision has no teeth: "If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is of the sort shielded from review." *Amgen*, 357 F.3d at 113.

provided to ESRD patients—including drugs that are not furnished to treat ESRD at all but instead are furnished to treat conditions like asthma, HIV, and arthritis. Such a definition would plainly violate the statute, but under Defendants' interpretation of subparagraph (G), it would be entirely unreviewable. That cannot be right.

Unsurprisingly, this Court has repeatedly rejected similar arguments by agency counsel. *See, e.g.*, *Am. Hosp. Ass'n*, 964 F.3d at 1237-39; *Amgen*, 357 F.3d at 111-14; *see also COMSAT*, 114 F.3d at 227 (describing similar argument as "preposterous"). Defendants strive to distinguish *American Hospital Association* and *Amgen* on the ground that the statutes at issue there "expressly cross-referenced" the definitional provision. Opp. to Emergency Stay Appl. 17 n.1. But as the district court explained, that purported distinction is factually dubious and, regardless, a distinction without a difference. JA171-72 (MTD Op. 17-18). The statute in *Amgen*, like the statute in this case, lacked any "explicit link" between the jurisdictional provision and the subsection of the statute defining the key term. *Id.* Regardless, "as in *Amgen* . . . the link [here] is sufficiently implied." JA172. The essential point is that in both cases, Congress defined the key term (here, "renal dialysis services"),

and only agency actions that fall within that defined term are precluded from review. *Id.*

Thus, for all those reasons, this Court can and should proceed to the merits and determine whether CMS's oral-only drug rule constitutes a valid identification of "renal dialysis services" under the statute.

II. ORAL-ONLY DRUGS ARE NOT "RENAL DIALYSIS SERVICES"

This Court's interpretation "start[s] with the plain meaning of the text, looking to the 'language itself, the specific context in which that language is used, and the broader context of the statute as a whole.'" *Blackman v. District of Columbia*, 456 F.3d 167, 176 (D.C. Cir. 2006) (citation omitted). Even where an agency is involved, courts are obligated to exercise their independent judgment in determining the "best reading" of the statute, *i.e.*, the "'reading the court would have reached' if no agency were involved." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 373 (2024) (citation omitted).

Here, that reading is Plaintiffs': oral-only drugs that are provided neither during dialysis nor by dialysis facilities are not "renal dialysis services," and thus do not belong in the ESRD PPS bundle. The district court reached the opposite conclusion only by adopting a reading of subpart (B)(iii) of the statute that CMS has never adopted and that would exclude many drugs currently in the bundle—a problem the district court then attempted to fix by reading the statute to allow CMS

to define new categories of "renal dialysis services" beyond the four specific categories that Congress laid out. That interpretation, which would leave CMS with essentially unbounded authority to circumvent the statute, should be rejected.

A. The Statute Defines Four, Non-Overlapping Categories of Renal Dialysis Services And Oral-Only Drugs Do Not Fit Into Any Of Them

Congress's definition of "renal dialysis services" consists of four subparts:

> (i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;
>
> (ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;
>
> (iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and
>
> (iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

42 U.S.C. § 1395rr(b)(14)(B). Oral-only drugs fall within none of those subparts.

1. All Agree That Subparts (B)(i) And (B)(ii) Do Not Encompass Oral-Only Drugs

It is undisputed that neither oral-only drugs in general, nor XPHOZAH in particular, fall within the scope of subpart (B)(i) or (B)(ii). *See* 74 Fed. Reg. at 49922; 75 Fed. Reg. at 49030. Clause (i) is limited to "[i]tems and services" already

included in the "composite rate for renal dialysis services," as of December 31, 2010, at which point, oral-only drugs were not included. 75 Fed. Reg. at 49036. Meanwhile, clause (ii) is limited to "[e]rythropoiesis stimulating agents" (drugs that stimulate the production of red-blood cells) and "any oral form of such agents," thereby excluding XPHOZAH and other oral-only drugs that are not ESAs. *See id.* CMS has never argued that oral-only drugs fall within either of these two clauses.

2. Subpart (B)(iii) Does Not Encompass Oral-Only Drugs

In its rulemaking, CMS principally relied on subpart (B)(iii), which covers "other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title"—*i.e.*, outside the composite rate system—"and any oral equivalent form of such drug or biological." 42 U.S.C. § 1395rr(b)(14)(B)(iii). Despite that nuanced definition, CMS interpreted this provision "to include *all* drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, *regardless of the route of administration*." 74 Fed. Reg. at 49928 (emphasis added); 75 Fed. Reg. at 49038 (same). CMS thus interpreted "renal dialysis services" to include "drugs . . . with

only an oral form," like XPHOZAH. 42 C.F.R. § 413.171(3). That interpretation is untenable under the text, legislative history, and statutory purpose of MIPPA.

a. Text: Contrary to CMS's regulation, subpart (B)(iii) does not define "renal dialysis services" to include *all* drugs. Rather, it covers only a particular subset of drugs: "other drugs" furnished "for the treatment of end stage renal disease"—*i.e.*, "other" drugs not included in subparts (B)(i) or (ii)—"for which payment was (before the application of this paragraph) made separately under this [title]," as well as "any oral *equivalent* form *of such drug or biological*." 42 U.S.C. § 1395rr(b)(14)(B)(iii) (emphasis added). Subpart (b)(iii) thus reaches only "oral" drugs that are the "*equivalent*" of the "other drugs and biologicals" for which payment was previously made outside of the composite rate system. *Id.* (emphasis added). CMS's regulation misreads that provision to cover *all* oral drugs, even those with no biological or injectable "equivalent" that was previously paid for separately.

CMS itself recognized that "an alternative reading of the last part of clause (iii) with respect to the phrase 'and any oral equivalent form of such drug or biological' could be interpreted to limit the scope of the drugs and biologicals included in the bundle to only oral versions of injectables." 74 Fed. Reg. at 49928 (citation omitted). CMS disagreed with that reading as a matter of policy,[8]

[8] Ironically, CMS's policy concerns were backwards. Numerous stakeholders, from patient groups to physicians to drug manufacturers to dialysis providers, have repeatedly warned CMS that the inclusion of oral-only drugs in the bundle will

dismissing it as "unduly constrained." *Id.* But CMS made no effort to explain how its alternative construction fit with the text of subpart (B)(iii). That was improper. CMS was not free to "rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014).

Yet that is exactly what CMS did. In effect, CMS removed the struck through language below from the statute and replaced it with the bolded regulatory text.

> Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (~~and any oral equivalent form of such drug or biological~~ **including drugs and biologicals with only an oral form**) . . . .

42 C.F.R. § 413.171(3).

Had Congress intended subpart (B)(iii) of the definition to cover "all drugs and biologicals that treat ESRD," it could easily have said so, using far fewer and simpler words. *See Wint v. Yeutter*, 902 F.2d 76, 82 (D.C. Cir. 1990) (agency properly eschewed "all-inclusive definition" because "Congress could have said simply 'all plaints' if Congress had indeed meant just that"). It did not. It should be unsurprising, therefore, that "many comment[er]s" criticized CMS's interpretation of subpart (B)(iii) as "a misreading of statutory intent" that "violates principles of statutory construction." 75 Fed. Reg. at 49038. Fundamentally, the "best reading"

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undermine health outcomes and harm patients. JA75 (Clynes Decl. ¶ 35); JA83 (Puckrein Decl. ¶ 30); JA101 (Williams Decl. ¶¶ 77-78); *see infra* at 40-42.

of subpart (B)(iii) excludes oral-only drugs. *Loper Bright*, 603 U.S. at 373. CMS's contrary regulatory construction should be rejected.[9]

b. Purpose: Plaintiffs' reading of subpart (B)(iii) best accords with MIPPA's purpose. As all parties agree, MIPPA was designed to promote the cost-effective provision of renal dialysis services by dialysis facilities. When MIPPA was enacted, however, oral-only drugs neither were provided by dialysis facilities during dialysis, nor were the equivalent of injectable drugs that were. JA94 (Williams Decl. ¶ 45). Thus, the inclusion of oral-only drugs would not have advanced Congress's goals of deterring dialysis facilities from "overus[ing] [then-]profitable separately billable drugs." 75 Fed. Reg. at 49032. Instead, Congress intended to promote "operational efficiency" by incorporating into the definition of "renal dialysis services" the kinds of drugs then employed at those facilities—*i.e.* injectable drugs and biologicals administered intravenously during dialysis—and their oral equivalents. *See id.*

Moreover, despite CMS's argument that including oral-only drugs in the bundle would advance MIPPA's policy, doing so will actually harm patients with

[9] In addition to creating superfluity within clause (iii), CMS's regulatory interpretation would create superfluity with clause (ii). Interpreting clause (iii) to exclude oral-only drugs accords with Congress's choice in clause (ii) to specifically instruct that ESAs, and any oral form of such agents, are encompassed within the definition. Had Congress intended for *all* oral treatments provided to ESRD patients to be encompassed, there would have been no need to specify that renal dialysis services extend to "erythropoiesis stimulating agents *and any oral form of such agents*." 42 U.S.C. § 1395rr(b)(14)(B)(iii) (emphasis added).

ESRD, as dozens of organizations representing every spoke of the kidney-care community explained. *See id.* (CMS acknowledging that "[m]ost" commenters opposed the rule because it "would lead to poorer patient outcomes"); JA75 (Clynes Decl. ¶¶ 32-35); JA83 (Puckrein Decl. ¶¶ 26-31).

Real-world evidence shows that access to novel drugs routinely drops precipitously once those drugs are included in the bundle. For example, after Parsabiv, a novel intravenous drug that treats secondary hyperparathyroidism, was permanently added to the ESRD bundle, usage dropped from a former high of over 10% of ESRD patients to less than 1%. JA100-01 (Williams Decl. ¶ 75). And other manufacturers have ceased development of innovative therapies because of a drug's likely placement into the bundle. *See* JA101-02 (*id.* ¶ 80).

Not only that, placing oral-only drugs into the bundle will also increase the cost to patients who are ill-suited to pay it. Indeed, CMS itself admits that placing oral phosphate binders into the bundle will impose $130 *million* in additional costs on ESRD patients who are disproportionately low income and unemployed. *See* 89 Fed. Reg. 55760, 55827 (July 5, 2024). Ultimately, the lack of access caused by CMS's rule will disproportionately harm patients from minority, rural, and low-

income backgrounds, who make up a significant share of the population suffering from ESRD and who will be directly impacted by this rule. *Id.*[10]

c. Legislative History: Notably, Congress expressly considered and *rejected* legislation that would have amended subpart (B)(iii) to expand the definition of "renal dialysis services" to include oral-only drugs. One year after the enactment of MIPPA, the House of Representatives introduced a bill that would have amended subpart (B)(iii) to read as follows (*italicized text* would have been added):

> (iii) Other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological *including oral drugs that are not the oral equivalent of an intravenous drug (such as oral phosphate binders and calcimimetics)*.

America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 1232 (2009) (emphasis added); *compare* 42 U.S.C. § 1395rr(b)(14)(B)(iii). But Congress chose not to adopt this statutory language, which would have adopted CMS's preferred construction of subpart (B)(iii) and extended that definition to "oral drugs that are not the oral equivalent of an intravenous drug." The fact that Congress

[10] The district court suggested that CMS's regulation may expand access to certain drugs because roughly 20% of Medicare patients do not have Medicare Part D, which prior to CMS's regulation, covered payment for oral-only drugs like XPHOZAH. But many of those patients were *already* receiving oral-only drugs like XPHOZAH through other insurance sources or financial-hardship programs. JA153 (Williams Suppl. Decl. ¶ 23 (Dkt. 20-1)). And CMS's rule will indisputably *reduce* access for the roughly 80% of patients who do have Medicare Part D. JA73-75 (Clynes Decl. ¶¶ 24-35), JA152-53 (Williams Suppl. Decl. ¶¶ 20-24).

considered but did not adopt a proposal to specifically include oral-only drugs in the ESRD PPS further underscores that CMS's contrary construction is inconsistent with MIPPA's language. *Cf. INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) ("Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." (citation omitted)).

For all those reasons, subpart (B)(iii) is best read not to cover oral-only drugs.

3. Subpart (B)(iv) Does Not Encompass Oral-Only Drugs

Finally, CMS briefly pointed to subpart (B)(iv) as justification for its rule, *see* 75 Fed. Reg. at 49040; 74 Fed. Reg. at 49928, but oral-only drugs do not fall into that clause either.

Subpart (B)(iv) directs CMS to include in the bundle "diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease." 42 U.S.C. § 1395rr(b)(14)(B)(iv). In its 2011 rulemaking, CMS suggested clause (iv) "can be interpreted as a residual or catch all category for drugs which do not fall under the scope of those renal dialysis services identified in clauses (ii) and (iii)," including oral-only drugs that "do not fall under the scope of those specified renal dialysis services identified in clauses (ii) and (iii)." 75 Fed. Reg. at 49039.

CMS's "catch-all" reading of clause (iv) is impermissible because it negates Congress's choice to enumerate specific categories of drugs. Congress chose to reference particular "oral" or "oral equivalent" forms of "*such*" drugs or agents—which means that these are the *only* oral drugs covered. 42 U.S.C. § 1395rr(b)(14)(B); *see, e.g.*, Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 107 (2012) ("Negative-Implication Canon[:] The expression of one thing implies the exclusion of others . . . ."); *Jennings v. Rodriguez*, 583 U.S. 281, 300 (2018) (same). If Congress intended *all* drugs (or even all *oral* drugs) furnished to individuals for the treatment of ESRD to qualify as "renal dialysis services," there would have been no need to more narrowly define other drugs, biologicals, and oral equivalent forms of such drugs and biologicals covered by the statute in clauses (ii) and (iii).

Put another way, if clause (B)(iv) was interpreted as CMS has suggested, it would render clauses (ii) and (iii) superfluous: Any drug, biological, or oral equivalent form that falls within clauses (ii) and (iii) necessarily would qualify as "items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease." 42 U.S.C. § 1395rr(b)(14)(B)(iv); *see Air Transp. Ass'n of Am., Inc. v. U.S. Dep't of Agric.*, 37 F.4th 667, 672 (D.C. Cir. 2022) ("'It is a familiar canon of statutory construction that, "if possible," we are to construe a statute so as to give effect to "every clause and word."'" (citation

omitted)); *Obduskey v. McCarthy & Holthus LLP*, 586 U.S. 466, 476 (2019) (courts "presum[e]" that laws do not contain "surplusage" (alteration in original) (citation omitted)).

CMS appeared to recognize, in response to comments, that it would "violate[] a principle of statutory construction [to] mak[e] clauses (ii) and (iii) otherwise redundant." 75 Fed. Reg. at 49039. To that end, it conceded that clause (iv) "does not mean all drugs currently available to Medicare beneficiaries for the treatment of ESRD." *Id.* But it believed that clause (iv) "can be interpreted as a residual or catch all category for drugs which do not fall under the scope of those specified renal dialysis services identified in clauses (ii) and (iii)." *Id.* That ignores clause (iv)'s actual language, which speaks to "laboratory tests and other items and services not described in *clause (i)*," not to drugs which are not described in *clause* (*ii*) and *clause* (*iii*). *Id.* at 49040 (emphasis added). Clause (iv) therefore cannot be interpreted to encompass all drugs not encompassed in clause (i) (including oral-only drugs) without rendering clause (ii) and (iii) utterly redundant and superfluous.

In *Fischer v. United States*, the Supreme Court confronted a related "surplusage problem." 603 U.S. 480, 495 (2024). At issue were two subsections—one that described "particular types" of conduct in "specific terms," with another "broader" provision going beyond the first. *Id.* at 486; *see* 18 U.S.C. § 1512(c)(1)-(2). The question was whether the second subsection was best read as linked with

(and limited by) the first subsection. *See Fischer*, 603 U.S. at 486. The Court's answer was "yes." Because "Congress would not go to the trouble of spelling out the list in (c)(1) if a neighboring term swallowed it up, the most sensible inference is that the scope of (c)(2) is defined by reference to (c)(1)." *Id.* at 490. So too here. If CMS's reading is right, "there would have been scant reason for Congress to provide any specific examples at all" in clauses (ii) and (iii). *Id.* at 490. The "sweep" of clause (iv) "would consume" clauses (ii) and (iii), "leaving th[ose] narrower provision[s] with no work to do." *Id.*

CMS's expansive alternative reading of clause (iv) also contradicts the canon of *ejusdem generis*, the principle that "'a general or collective term' at the end of a list of specific items' is typically 'controlled and defined by reference to the specific classes . . . that precede it.'" *Fischer*, 603 U.S. at 488 (alteration in original) (citation omitted). Here, Congress signaled the narrower scope of clause (iv) by addressing it to cover "*diagnostic laboratory tests* and other items and services not [covered by] clause (i)." 42 U.S.C. § 1395rr(b)(14)(B)(iv) (emphasis added). Particularly in light of a statutory scheme in which clauses (ii) and (iii) carefully specify only certain categories of drugs, clause (iv) is best read to encompass "objects similar in nature to those objects enumerated by the preceding specific words." *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 114-15 (2001) (citation omitted); *see also* 75 Fed. Reg. at 49064 (indicating that "[o]ther items and services" could be read more narrowly

to mean "[o]ther items and services separately billed by ESRD facilities that are used *in conjunction* with injectable medications or laboratory tests, such as blood products, syringes, and other dialysis supplies that are billed on Medicare outpatient institutional claims" (emphasis added)). This Court should not endorse CMS's broad reading of clause (iv), which *CMS itself* recognized would render the statutory definition "overlapping or redundant." 75 Fed. Reg. at 49040.

* * *

In short, oral-only drugs do not fit within any of the four specific categories of items covered by Congress's definition of "renal dialysis services." Accordingly, CMS's regulation should be invalidated as in excess of its statutory authority.

B. The District Court's Novel Interpretation Of Subpart (B)(iii) Makes No Sense And Cannot Save CMS's Regulation

The district court's construction of 42 U.S.C. § 1395rr(b)(14)(B)(iii) is a stark departure from the Government's own interpretation[11] of the statute and strays far from the plain reading of the text and structure of the statute. The district court divided subpart (B)(iii) into two clauses. It interpreted the first clause to "move drugs in all forms that exist under a fee-for-service reimbursement system prior to

[11] At the reconsideration stage, the court suggested that Plaintiffs' critique of its statutory reading was "at least in part, belated." JA230 (Mem. Op. Denying Mot. Alter. J. 19). That was incorrect. Plaintiffs set forth how MIPPA should be read. Plaintiffs' arguments on reconsideration simply responded to the court's novel, incorrect reading of the statute's text and structure—an interpretation that differed from CMS's own historical interpretation.

'application of this paragraph' into the bundle." JA177 (MTD Op. 23) (citation omitted). The court reasoned that because CMS's "*regulation* . . . does not go into effect with respect to oral-only drugs until January 1, 2025," "'this paragraph' has not yet been applied to oral-only drugs." *Id.* (emphasis added) (citation omitted).[12] On that basis, the court concluded that oral-only drugs that currently exist and are separately reimbursed by CMS prior to January 1, 2025 may be "moved into the bundle." *Id.*

The court went on to hold that the "first clause of subpart (B)(iii) says nothing . . . about drugs that only come into existence *after* 'application of this paragraph,'" which is "where the second part of (B)(iii) does work." *Id.* (citation omitted). In particular, the court held that the second clause of (B)(iii) contemplates that "renal dialysis services" include "new, subsequently-developed oral versions of drugs, which were extant in a different form at the time (B)(iii) was applied and were moved into the bundle." *Id.* In the district court's view, therefore, subpart (B)(iii) covers new drugs that are "the oral equivalent form" of injectable drugs or biologicals that were separately reimbursed prior to the application of (B)(iii) to such drugs, on January 1, 2011.

[12] That even conflicts with CMS's own reading of "this paragraph" to mean "before 2011." JA232 (Mem. Op. Denying Mot. Alter. J. 21 & n.6). The court dismissed CMS's contemporaneous regulatory determination as "irrelevant" under *Loper Bright*. *Id.*

Under the court's view, Congress created a nonsensical, complex patchwork quilt of what drugs are included in the bundle under (B)(iii):

	Approved[13] Before Jan. 1, 2011	**Approved from Jan. 1, 2011 to Jan. 1, 2025**	**Approved After Jan. 1, 2025**
Injectable	Yes	No	No
Biological	Yes	No	No
Oral-Only	Yes	Yes	No
Oral Equivalent of Injectable / Biological Approved Before Jan. 1, 2011	Yes	Yes	Yes
Oral Equivalent of Injectable / Biological Approved After Jan. 1, 2011	N/A	No	No

That reading of subpart (B)(iii) would *exclude* many drugs that are currently in the bundle. CMS, for instance, currently includes in the bundle multiple injectable drugs that were first approved *after* 2011 and for which CMS never paid separately, such as Parsabiv and Korsuva. *See* JA100-02 (Williams Decl. ¶¶ 75, 80). Under the district court's interpretation, those drugs would not fall under the first clause of subpart (B)(iii). And because they are injectable drugs, not "oral equivalent[s],"

[13] The dividing line technically turns on whether CMS paid separately for a given drug on a given date, which roughly corresponds to the date of approval.

they would not fall under the second clause either. Accordingly, they are not covered by subpart (B)(iii). The same is true for oral-only drugs approved *after* January 1, 2025. JA177 (MTD Op. 23). That too conflicts with the construction of subpart (B)(iii) that CMS long ago adopted. *See* 74 Fed. Reg. at 49928 (rejecting interpretation of (B)(iii) that would exclude "*new* oral-only drugs and biologicals") (emphasis added).

In summary, the district court's construction of subpart (B)(iii) is significantly at odds with CMS's own historical construction of that provision. As subpart (B)(iii) has been interpreted by the district court, CMS may add new treatments to the ESRD PPS bundle after January 1, 2025 only when they are the "oral equivalent form" of an injectable drug or biological for which separate payment was made prior to January 1, 2011. Under that result, CMS can no longer justify its inclusion in the bundle under subpart B(iii) injectable and biological drugs approved after January 1, 2011. And CMS could not add to the bundle any oral-only drugs newly launched after January 1, 2025. There is no conceivable reason why Congress would have intended to legislate that confusing patchwork, which is totally at odds with the purposes underlying MIPPA. Neither CMS nor the district court offered any plausible theory for why Congress would have written subpart B(iii) in this inexplicable manner.

By contrast, reading subpart (B)(iii) in the manner for which Plaintiffs have advocated produces a far more straightforward and intuitive result, which better accords with the government's past practice and the statute's text and purpose. Under Plaintiffs' interpretation, the phrase "for which payment was (before the application of this paragraph) made separately under this subchapter," 42 U.S.C. § 1395rr(b)(14)(B)(iii), simply provides for the inclusion of types of drugs for which payment was made separately under the system that existed prior to MIPPA (i.e. the payment system that existed "before the application of this paragraph"). Since injectable and biological drugs were paid for separately under the prior system, they are covered by the first clause. Properly understood, therefore, the first clause of subpart (B)(iii) includes all injectable drugs and biologicals that treat ESRD, whenever first marketed. The second clause of subpart (B)(iii), by extension, extends the definition of "renal dialysis services" to cover the oral equivalent forms of injectable drugs and biologicals that a dialysis facility would otherwise administer during dialysis, as summarized in this chart:

	Approved Before Jan. 1, 2011	Approved from Jan. 1, 2011 to Jan. 1, 2025	Approved After Jan. 1, 2025
Injectable	Yes	Yes	Yes
Biological	Yes	Yes	Yes
Oral-Only	No	No	No
Oral Equivalent of Injectable / Biological	Yes	Yes	Yes

Unlike the district court's construction of subpart (B)(iii), Plaintiffs' construction would not exclude drugs that CMS currently includes under subpart (B)(iii), nor would it hamstring CMS from including future injectable drugs or biologicals under subpart (B)(iii). Rather, it would just exclude oral-only drugs, a result which is entirely consistent with MIPPA's text and purpose.

C. The Statute's Use Of The Word "Includes" Does Not Allow CMS To Abrogate Congress's Four Specific Categories

In an attempt to fix the problems generated by its interpretation of subpart (B)(iii), the district court relied on the opening language of subparagraph (B), which states: "For purposes of this paragraph, the term 'renal dialysis services' *includes* [the four enumerated categories]." 42 U.S.C. § 1395rr(b)(14)(B) (emphasis added). The district court read this language to mean that subparts (B)(i)-(iv) were "non-exhaustive," and CMS therefore had authority to define as renal dialysis services "other items or services not generally described in subparagraph (B) *at all*." JA217,

223 (Mem. Op. Denying Mot. Alter. J. 6, 12) (emphasis added); *see* JA175-76 (MTD Op. 21-22). That interpretation is untenable for at least three reasons.

First, the Supreme Court and this Court have rejected the view that "includes" should be read to convey unbounded authority to ignore Congress's specific directives. Where Congress "explicitly and comprehensively defined the term by including only three"—or here, four—"discrete definitions," the word "includes" cannot be read as an open-ended invitation to the agency to supplement that definition. *Carcieri v. Salazar*, 555 U.S. 379, 391-92 (2009); *see also Dong v. Smithsonian Inst.*, 125 F.3d 877, 880 (D.C. Cir. 1997) (finding Congress's use of "includes" did not amount to an "invitation to extend [the statutory definition] to [objects] that do not belong among the types enumerated").

Second, even assuming Congress's use of "includes" could be read to afford CMS some sort of residual authority to expand on the four clauses of subparagraph (B), CMS cannot use that authority to define "renal dialysis services" to encompass drugs necessarily excluded from those four clauses, as that would negate the limitations Congress imposed. *See, e.g.*, *Fin. Plan. Ass'n v. SEC*, 482 F.3d 481, 489-91 (D.C. Cir. 2007) (explaining that an agency cannot use a catch-all provision to "redefine or otherwise avoid specific requirements in [the] existing statutory exceptions"). If the district court is correct that Congress made such nuanced determinations about what drugs were and were not covered under subpart (B)(iii),

it would be absurd to read the use of "includes" as granting the agency free rein to ignore those nuanced decisions. Defendants have never explained why Congress would have set up such a complicated framework in subpart (B)(iii) only for that framework to be rendered meaningless by the agency's unbridled authority under the introductory clause to subparagraph (B). Simply put, even where "'includes'" sets forth examples, unenumerated items "must fit th[e] same mold" and cannot "break[]" it. *United States v. Brock*, 94 F.4th 39, 57 (D.C. Cir. 2024).

CMS's inclusion of oral-only drugs like XPHOZAH in the ESRD PPS bundle cannot be reconciled with the principles and limitations embodied in MIPPA's text. CMS long ago admitted that MIPPA "addresses payments to dialysis facilities for dialysis services." 75 Fed. Reg. at 49038. CMS at minimum, therefore, cannot redefine "renal dialysis services" to include categories of drugs that are not administered by dialysis facilities, nor during renal dialysis, and which the FDA has cautioned should not be taken before dialysis.

Third, even if the district court's reading of "includes" were correct, CMS expressly justified its oral-only drugs regulation solely under subpart (B)(iii) and (B)(iv), not some freestanding power to expand on Congress's definition beyond the four enumerated categories. *See id.* at 49038-39. Under *SEC v. Chenery Corp.*, "[t]he grounds upon which an administrative order must be judged are those upon

which the record discloses that its action was based." 318 U.S. 80, 87 (1943). Therefore, CMS cannot now rely on the "includes" language to justify its rule.

III. XPHOZAH IS NOT A RENAL DIALYSIS SERVICE

Finally, even if this Court agrees with the district court that oral-only drugs can be included in the ESRD PPS bundle under subpart (B)(iii), XPHOZAH cannot be because it is not a drug "furnished to individuals for the treatment of end stage renal disease." 42 U.S.C. § 1395rr(b)(14)(B)(iii)-(iv); 42 C.F.R. § 413.171(3)-(4). Specifically, XPHOZAH is furnished to treat hyperphosphatemia, not ESRD.

While hyperphosphatemia occurs in many patients with ESRD, individuals can have hyperphosphatemia without ESRD (and vice versa). The conditions are correlated, but not the same. That is true for many other conditions, but CMS generally recognizes that oral medications that treat those other causes of, complications from, or comorbidities of, ESRD are *not* "renal dialysis services." For instance, 84 percent of ESRD patients on dialysis also suffer from hypertension—a greater number than the percentage of ESRD patients with hyperphosphatemia. JA88-89 (Williams Decl. ¶¶ 13, 18). But CMS does not classify drugs treating hypertension as "renal dialysis services." *See* JA114-34 (Williams Decl. Ex. 2 (Dkt. 14-5)); *see also* 75 Fed Reg. at 49039. And although ESRD is associated with comorbidities ranging from diabetes and hypertension, to stroke, hepatitis, and cardiovascular disease, *see* JA88-89 (Williams Decl. ¶¶ 12-14), CMS does not

consider drugs that treat those comorbidities to be drugs "for the treatment of end stage renal disease" either, *see* 75 Fed Reg. at 49047; JA89 (Williams Decl. ¶ 16). Indeed, diabetes and hypertension are not just associated with ESRD, they are the two leading causes of it in the United States.[14] Yet, despite that relationship, CMS has determined that oral-only "drugs and biologicals used to treat diabetes, cardiac conditions and hypertension" should not be treated as "renal dialysis services." 75 Fed. Reg. at 49047.

Ultimately, CMS's decision to consider XPHOZAH as for the treatment of ESRD is at odds with the statute and CMS's treatment of other cases. CMS appears not to have asked whether XPHOZAH was "for the treatment of ESRD," 42 C.F.R. § 413.171(3)-(4), but rather whether it was "ESRD-*related*." 75 Fed. Reg. at 49039 (emphasis added); *see* JA59-61 (Compl. Ex. 1) (discussing whether the drug treats a "condition associated with ESRD"). That impermissibly expands the statutory definition of "renal dialysis services" by sidestepping whether a drug is for "the treatment of ESRD." 42 C.F.R. § 413.171(3)-(4); 42 U.S.C. § 1395rr(b)(14)(B)(iii)-(iv). The district court rejected this argument on essentially the same basis,

[14] *See, e.g.*, Peter N. Van Buren & Jula K. Inrig, *Hypertension and hemodialysis: pathophysiology and outcomes in adult and pediatric populations*, Pediatric Nephrology (Mar. 2012) (manuscript), https://pmc.ncbi.nlm.nih.gov/articles/PMC3204338/pdf/nihms303436.pdf; Ctrs. for Disease Control & Prevention, *Kidney Failure & Diabetes* (May 15, 2024), https://www.cdc.gov/diabetes/data-research/research/kidney-failure-diabetes.html; JA151 (Williams Decl. ¶ 12).

emphasizing that ESRD and hyperphosphatemia "are closely related" because hyperphosphatemia is most commonly caused by chronic kidney disease. JA183 (MTD Op. 29). But again, many other conditions are closely related to ESRD, yet they are not ESRD and the drugs that treat those other conditions do not treat ESRD. Thus, at an absolute minimum, the district court's conclusion that CMS did not exceed its statutory authority in defining XPHOZAH as a renal dialysis service should be reversed.

CONCLUSION

For the foregoing reasons, the district court's judgment should be reversed and summary judgment entered on Plaintiffs-Appellants' behalf.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with Federal Rule of Appellate Procedure 32(f) and (g), along with the Court's December 31, 2024 Order, because it contains 12,989 words.

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word and Times New Roman 14-point font.

/s/ Michael E. Bern
Michael E. Bern

ADDENDUM

Pursuant to Rule 28(a)(5)

TABLE OF CONTENTS

42 U.S.C. § 1395rr

§ 1395rr. End stage renal disease program

* * *

(b) Payments with respect to services; dialysis; regulations; physicians' services; target reimbursement rates; home dialysis supplies and equipment; self-care home dialysis support services; self-care dialysis units; hepatitis B vaccine

* * *

(14)(A)(i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this subchapter to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).

(ii) In implementing the system under this paragraph the Secretary shall ensure that the estimated total amount of payments under this subchapter for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments for renal dialysis services, including payments under paragraph (12)(B)(ii), that would have been made under this subchapter with respect to services furnished in 2011 if such system had not been implemented. In making the estimation under subclause (I), the Secretary shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization.

(B) For purposes of this paragraph, the term "renal dialysis services" includes—

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Such term does not include vaccines.

(C) The system under this paragraph may provide for payment on the basis of services furnished during a week or month or such other appropriate unit of payment as the Secretary specifies.

(D) Such system—

(i) shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors;

(ii) shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management;

(iii) shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent; and

(iv) may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—

(I) for pediatric providers of services and renal dialysis facilities;

(II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and

(III) for providers of services or renal dialysis facilities located in rural areas.

The Secretary shall take into consideration the unique treatment needs of children and young adults in establishing such system.

(E)(i) The Secretary shall provide for a four-year phase-in (in equal increments) of the payment amount under the payment system under this paragraph, with such payment amount being fully implemented for renal dialysis services furnished on or after January 1, 2014.

(ii) A provider of services or renal dialysis facility may make a one-time election to be excluded from the phase-in under clause (i) and be paid entirely based on the payment amount under the payment system under this paragraph. Such an election shall be made prior to January 1, 2011, in a form and manner specified by the Secretary, and is final and may not be rescinded.

(iii) The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such phase-in.

(F)(i)(I) Subject to subclauses (II) and (III) and clause (ii), beginning in 2012, the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. In order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the increase factor described in the preceding sentence for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018.

(II) Subject to subclause (III), for 2012 and each subsequent year, after determining the increase factor described in subclause (I), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title. The application of the preceding sentence may result in such increase factor being less than 0.0 for a year, and may result in payment rates under the payment system under this paragraph for a year being less than such payment rates for the preceding year.

(III) Notwithstanding subclauses (I) and (II), in order to accomplish the purposes of subparagraph (I) with respect to 2015, the increase factor described in subclause (I) for 2015 shall be 0.0 percent pursuant to the regulation issued by the Secretary on December 2, 2013, entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule" (78 Fed. Reg. 72156).

(ii) For years during which a phase-in of the payment system pursuant to subparagraph (E) is applicable, the following rules shall apply to the portion of the payment under the system that is based on the payment of the composite rate that would otherwise apply if the system under this paragraph had not been enacted:

(I) The update under clause (i) shall not apply.

(II) Subject to clause (i)(II), the Secretary shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i)(I).

(G) There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the determination of payment

amounts under subparagraph (A), the establishment of an appropriate unit of payment under subparagraph (C), the identification of renal dialysis services included in the bundled payment, the adjustments under subparagraph (D), the application of the phase-in under subparagraph (E), and the establishment of the market basket percentage increase factors under subparagraph (F).

(H) Erythropoiesis stimulating agents and other drugs and biologicals shall be treated as prescribed and dispensed or administered and available only under part B if they are—

(i) furnished to an individual for the treatment of end stage renal disease; and

(ii) included in subparagraph (B) for purposes of payment under this paragraph.

(I) For services furnished on or after January 1, 2014, and before January 1, 2015, the Secretary shall, by comparing per patient utilization data from 2007 with such data from 2012, make reductions to the single payment that would otherwise apply under this paragraph for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of drugs and biologicals described in clauses (ii), (iii), and (iv) of subparagraph (B) (other than oral-only ESRD-related drugs, as such term is used in the final rule promulgated by the Secretary in the Federal Register on August 12, 2010 (75 Fed. Reg. 49030)). In making reductions under the preceding sentence, the Secretary shall take into account the most recently available data on average sales prices and changes in prices for drugs and biological[2] reflected in the ESRD market basket percentage increase factor under subparagraph (F).

* * *

[2] So in original. Probably should be "biologicals".

42 C.F.R. § 413.171

§ 413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix adjustments and any ESRD facility adjustments, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in § 413.174(b) and (c) of this chapter), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under § 410.50 and § 410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered "renal dialysis services," and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

42 C.F.R. § 413.174

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that --

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. CMS determines that a facility is hospital-based if the --

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider --

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in § 414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in § 414.313.

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

(1) Only on an assignment basis, directly to the facility which must accept, as payment in full, the amount that CMS determines;

(2) Subject to the Part B deductible and coinsurance;

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in § 414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in § 405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biological furnished by independent ESRD facilities is based on the methodology specified in § 414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in § 413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2025, I electronically filed the foregoing brief with the United States Court of Appeals for the District of Columbia Circuit through the Court's CM/ECF system. All parties are represented by registered CM/ECF users and will be served by the CM/ECF system.

/s/ Michael E. Bern
Michael E. Bern